فلم کوٹڈ گولیاں

موکسی زیک®

موکسی فلاکساسین ہائیڈروکلورائیڈ

وسیع العمل اینٹی بائیوٹک

خوراک:

دواڈاکٹر کی ہدایات کے مطابق استعمال کریں۔

ہدایات:

* دوا ٹھنڈی اور خشک جگہ پر رکھیں۔
* دوا کو گرمی، روشنی اور نمی سے محفوظ رکھیں۔
* تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

پیشکش:

موکسی زیک ۴۰۰ ملی گرام فلم کوٹڈ گولیاں (۱×۵) بلسٹر پیک میں دستیاب ہیں۔

Manufactured by:
Schazoo Zaka (Pvt) Ltd.
Kalalwala, 20-Km Lahore-Jaranwala Road,
Distt: Sheikhupura, Pakistan.

Film Coated Tablets

MoxiZak®

Moxifloxacin Hydrochloride

Broad Spectrum Antibiotic

COMPOSITION:
Each film coated tablet contains
Moxifloxacin (as HCl) Sch. Specs. 400mg

Properties:
Moxifloxacin is a fluoroquinolone with broad spectrum of activity and bactericidal action.

Microbiological Activity:
Moxifloxacin has in vitro activity against a wide range of Gram-positive and Gram-negative microorganisms, anaerobic, acid-fast bacteria, and atypicals e.g. Mycoplasma spp, Chlamydia spp and Legionella spp.
Moxifloxacin has been shown to be active against most of the strains of the following microorganisms.
Gram-positive microorganisms
Staphylococcus aureus, Streptococcus pneumoniae, Streptococcus pyogenes.
Gram-negative microorganisms
Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Moraxella catarrhalis, Escherichia coli, Enterobacter cloacae
Atypicals
Chlamydia pneumoniae, Mycoplasma pneumoniae.

The following organisms are sensitive to moxifloxacin, however, the safety and effectiveness of moxifloxacin in treating clinical infections due to these microorganisms has not been established.
Gram-positive microorganisms
Streptococcus milleri, Streptococcus mitior, Streptococcus agalactiae, Streptococcus dysgalactiae, Staphylococcus cohnii, Staphylococcus epidermidis, Staphylococcus haemolyticus, Staphylococcus hominis, Staphylococcus saprophyticus, Staphylococcus simulans, Corynebacterium diphtheriae.
Gram-negative microorganisms
Bordetella pertussis, Klebsiella oxytoca, Enterobacter aerogenes, Enterobacter agglomerans, Enterobacter intermedius, Enterobacter sakazaki, Proteus mirabilis, Proteus vulgaris, Morganella morganii, Providencia rettgeri, Providenica stuartii.
Anaerobes
Bacteroides distasonis, Bacteroides eggerthii, Bacteroides fragilis, Bacteroides ovatus, Bacteroides thetaiotaomicron, Bacteroides uniformis, Fusobacterium spp, Porphyromonas spp, Porphyromonas anaerobius, Porphyromonas asaccharolyticus, Porphyromonas magnus, Prevotella spp, Propionibacterium spp, Clostridium perfringens, Clostridium ramosum.
Atypicals
Legionella pneumophila, Caxiella burnettii

Pharmacokinetics:
Absorption:
Moxifloxacin is well absorbed from gastrointestinal tract after oral administration. The absolute bioavailability of moxifloxacin is approximately 90%. Co-administration with a high fat meal does not affects the absorption of moxifloxacin.
Plasma concentration increase proportionally with dose up to highest dose tested (1200mg single oral dose). The mean (± SD) elimination half life from plasma is 12±1.3 hours; steady-state is achieved after at least three days with 400mg once daily regimen.

Distribution:
Moxifloxacin is approximately 50% bound to serum proteins, independent of drug concentration. The volume of distribution of moxifloxacin ranges from 1.7 to 2.7 L/kg. Moxifloxacin is widely distributed throughout the body, with tissue concentrations often exceeding plasma concentrations.

Metabolism:
Approximately 52% of an oral dose of moxifloxacin is metabolized via glucuronide and sulfate conjugation. The cytochrome P_{450} system is not involved in moxifloxacin metabolism, and is not affected by moxifloxacin.

Excretion:
Approximately 45% of an oral dose of moxifloxacin is excreted as unchanged drug (~20% in urine ~25% in feces). A total of 96% ±4% of an oral dose is excreted as either unchanged drug or known metabolites. The mean (± SD) apparent total body clearance and renal clearance are 12 ± 2.0 L/hr and 2.6± 0.5 L/hr, respectively.

INDICATIONS:
MoxiZak tablets are indicated for the treatment of adult (≥ 18 years of age) with upper and lower respiratory tract infections such as
- Acute sinusitis
- Acute exacerbation of chronic bronchitis
- Community acquired pneumoniae
- Skin and soft tissue infections

DOSAGE & ADMINISTRATION
The dose of MoxiZak is 400mg once every 24 hours. The duration of therapy depends upon the type and severity of infection as given below

Infection	Daily Dose	Duration
Acute bacterial sinusitis	400mg	10 days
Acute bacterial exacerbation of Chronic Bronchitis	400mg	5 days
Community acquired pneumoniae.	400mg	7-14 days
Uncomplicated Skin and Skin Structure Infection	400mg	7 days
Complicated Skin and Skin Structure Infection	400mg	7-21 days

Elderly patients:
No dosage adjustment required in elderly patients.
Children:
The use of Moxifloxacin in children and adolescents in growth phase is not recommended.
Dosage in patients with renal impairment
No dosage adjustment required in renally impaired patients, including those on either hemodialysis or continuous ambulatory peritoneal dialysis.
Dosage in Patients with Hepatic impairment
No dosage adjustment required in patients with mild or moderate hepatic insufficiency.

CONTRA-INDICATIONS:
MoxiZak is contra-indicated in patients with history of hypersensitivity to Moxifloxacin or any member of the quinolone class of antimicrobial agent.

WARNINGS:
Moxifloxacin has been shown to prolong the QT interval of the electrocardiogram in some patients. The drug should be avoided in patients with known prolongation of the QT interval, patients with uncorrected hypokalemia and patients receiving Class IA (e.g. quinidine, procainamide) or Class IIIA (e.g. amiodarone, sotolol) antiarrythmic agents, due to lack of clinical experience with the drug in these patients populations.

PRECAUTIONS:
To assure safe and effective use of moxifloxacin, the following information and instruction should be communicated to the patient when appropriate;
Patients should be advised;
- That moxifloxacin tablets should be taken at least 4 hours before or 8 hours after multi-vitamins (containing iron or zinc), antacids (containing magnesium or aluminum), and sucralfate.
- That moxifloxacin may be associated with hypersensitivity reaction, including anaphylactic reaction, even following a single dose, and to discontinue the drug at the first sign of skin rash or other sign of allergic reaction.
- To discontinue treatment; rest and refrain from exercise; and inform their physician if they experience pain, inflammation, or rupture of a tendon.

PREGNANCY/ LACTATION:
MoxiZak should not be used in Pregnancy/Lactation.

DRUG INTERACTIONS:
The concomitant administration with ranitidine did not change the absorption characteristics of moxifloxacin significantly. Absorption parameters (C_{max}, T_{max}, AUC) were very similar indicating absence of an influence of gastric pH on moxifloxacin uptake from the gastro intestinal tract.
Concomitant ingestion of moxifloxacin together with antacid, mineral and multi-vitamins may result in impaired absorption of the drug due to formation of chelate complexes with the multi-valent cations contained in these preparations. Antacids and preparations containing magnesium, aluminum and other mineral such as iron should be administered at least 4 hours before or 2 hours after ingestion of an oral moxifloxacin dose.
No interaction during concomitant treatment with warfarin on prothrombin time and other coagulation parameter has been observed.
The pharmacokinetics of digoxin is not significantly influenced by moxifloxacin.
No clinical relevant interaction was seen between glibenclamide and moxifloxacin.
Phototoxicity has been reported with other quinolones. However, a study in human volunteers concluded that moxifloxacin has no measurable phototoxic potential.

ADVERSE REACTIONS:
The adverse effects reported are to be least possibly drug-related, occurring in greater than or equal to 2% of Moxifloxacin treated patients were: nausea (6%), diarrhea (5%), and dizziness (2%). Additional clinical relevant events are
Body as a whole: Abdominal pain, headache, asthenia, moniliasis, pain, allergic reaction.
Cardiovascular system: Tachycardia, palpitation, vasodilation, QT interval prolong and hypertension.
Nervous system: Insomnia, nervousness.
Digestive system: Vomiting, abnormal liver function test, dyspepsia, dry mouth, flatulence, oral moniliasis, constipation.
Musculoskeletal: Arthralgia, myalgia.
Skin and appendages: Rash, urticaria, pruritus, sweating.
Urogenital: Vaginal moniliasis, vaginitis, kidney function abnormal

OVERDOSE:
No reported cases of overdosage. In the event of overdosage, appropriate supportive treatment should be initiated.

STORAGE CONDITIONS:
* Store in a cool and dry place.
* Protect from heat, light and moisture.
* Keep all medicines out of the reach of children.

PRESENTATION:
MoxiZak 400mg film coated tablets are available in (1 x 5) blister pack.